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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/898,234	07/03/2001	Rudolf Hauptmann	98,385-I	5009

20306 7590 08/25/2005

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EXAMINER

O HARA, EILEEN B

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 08/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/898,234

Applicant(s)

HAUPTMANN ET AL.

Examiner

Eileen O'Hara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,23,41,42,45-48 and 50-62 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 42 is/are allowed.
- 6) ☒ Claim(s) 1,23,41,45 and 48-62 is/are rejected.
- 7) ☒ Claim(s) 46 and 47 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 07/511,430.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input checked="" type="checkbox"/> Other: ____ |

DETAILED ACTION

1.1 The indicated allowability of claims 1, 23, 41, 45-48 and 50-62 is withdrawn in view of the newly discovered reference(s) to Wallach et al., U.S. Patent No. 5,981,701. Rejections based on the newly cited reference(s) follow.

1.2 Claims 1, 23, 41, 42, 45-48 and 50-62 are currently pending and under examination.

Priority

2. This application is a continuation of 09/792,356, which is a continuation of 08/477,639, now patent 6,221,675, which is a division of 08/383,676, now patent 6,294,352, which is a continuation of 08,153,287, which is a continuation of 07/821,750, which is a division of This application is a continuation of 09/792,356, which is a continuation of 08/477,639, 07/511,430. The Examiner notes that certified copies of the German priority documents P39 13 101.7, P3290 282.8 and European priority document 90106624.1 were provided in 07/511,430. However, Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

The second application must be an application for a patent for an invention which is also disclosed in the first application (the parent or provisional application); the disclosure of the invention in the parent application and in the second application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38F.3d551, 32 USPQ 2d 1077 (Fed. Cir. 1994). The first priority document, 39 13 101 .7, filed April 21, 1989, contains only fragments of the claimed polypeptides. The second priority document, 3920 282.8, filed June 21, 1989, discloses a polypeptide comprising amino acids 1-371 of the amino acid sequence of the full-length

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polypeptide of SEQ ID NO: 2. The third foreign priority document, 90106624.2, filed April 6, 1990, discloses the entire amino acid sequence of SEQ ID NO: 2 (455 amino acids). SEQ ID NO: 4 is contained within the first 201 amino acids of SEQ ID NO: 2 (amino acids 41-201, and therefore the effective priority date for the polypeptide is June 21, 1989.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1, 23, 41, 45 and 48-62 are rejected under 35 U.S.C. 102(e) as being anticipate by Wallach et al., U.S. Patent No. 5,981,701, effective priority date Sept. 12, 1988, and Wallach et al., U.S. Patent No. 5,695,953, priority date Sept. 12, 1988.

Claims 1, 23, 41, 45 and 48-62 encompass a method for ameliorating the harmful effects of TNF in an animal, comprising administering to an animal a therapeutically effective amount of a recombinant polypeptide encoded by a nucleic acid molecule comprising the nucleotide sequence as set forth in SEQ ID NO: 3, or wherein the polypeptide comprises an amino acid sequence as set forth in SEQ ID NO: 4, wherein the polypeptide may have at least one additional amino acid at the carboxyl-terminus, and wherein the polypeptide may be chemically derivatized, and where in the polypeptide may be glycosylated.

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Wallach et al. teach the isolation of a TNF binding protein isolated from the urine of human patients, which has the N-terminal sequence shown on the page containing columns 3 and 4. The N-terminus of Wallach et al. corresponds to the N-terminus of SEQ ID NO: 4 of the instant invention, with the exception that amino acid 14 of Wallach is not identified. The substantially purified TNF binding protein of Wallach et al. has a molecular weight of about 26-28Kda when analyzed by SDS PAGE under reducing conditions and moves as a single peak on HPLC, and another patent to Wallach et al., 5,665,859, demonstrates that the full-length protein comprising the TNF binding protein of 5,981,701 is identical to the full-length protein of SEQ ID NO: 2 of the instant invention.

Patents 5,981,701 and 5,695,953 also teach that the protein is glycosylated (column 5, lines 26-30). Absent evidence to the contrary, this soluble TNF binding protein is identical to that of the protein of SEQ ID NO: 4 of the instant application. Although the claims recite a recombinant polypeptide, there is no evidence that a recombinantly produced polypeptide would differ from the protein of Wallach et al. Additionally, both 5,981,701 and 5,695,953 also teach that the protein can be produced recombinantly by host cells such as CHO cells, which would produce a glycosylated polypeptide (column 15, lines 24-46), and by prokaryotic cells, which produce a non-glycosylated polypeptide ((column 15, lines 11-23).

Since the USPTO does not have the resources to determine if the protein is different, and given the probability that the protein sequence of Wallach et al. is the same as that of SEQ ID NO: 4 of the instant application, the burden of proof falls to the Applicant to demonstrate a novel or unobvious difference between the claimed protein and that of the prior art. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray*, 10 USPQ 2d 1922 1923:

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“When claimed product and prior art product reasonably appear to be the same, the burden of proof is on Applicant to demonstrate a novel or unobvious difference between the claimed product and that of the prior art.”, and

In re Best, Bolton and Shaw, 1958 USPQ 430:

“The PTO can require applicant to prove that prior art products do not possess characteristics of the claimed product, where claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the burden of proof is on the applicant.”

Wallach et al. also teaches that the protein is glycosylated (column 5, lines 26-30), has the ability to inhibit the binding of TNF to its receptors, and the protein can be used to antagonize the deleterious effects of TNF (abstract, column 4, lines 18-23, column 16, lines 12-50), and that the protein can be chemically derivatized (column 4, lines 49-63). Therefore, Wallach et al. anticipates the claims.

Conclusion

4.1 Claim 42 is allowed.

4.2 Claims 46 and 47 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

4.3 Claims 1, 23, 41, 45 and 48-62 are rejected.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (571) 272-0878. The examiner can normally be reached on Monday through Friday from 10:00 AM to 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached at (571) 272-0829.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://portal.uspto.gov/external/portal/pair>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Eileen B. O'Hara, Ph.D.

Patent Examiner



EILEEN B. O'HARA
PATENT EXAMINER